

# Summary of Changes from v11.1 to v12.0

The COVID-19 situation is rapidly changing, and evidence is constantly accumulating. Therefore, we refer to the regularly updated BHIVA, DAIG, EACS, GESIDA & Polish Scientific AIDS Society Statement on risk of COVID-19 for [www.eacsociety.org/home/covid-19-and-hiv.html](http://www.eacsociety.org/home/covid-19-and-hiv.html)

## ART section

- Change the order of priority of the third drug associated with 2 NRTIs when starting ART: preferably a second generation INSTI or alternatively a PI/b
- Recommendations for Initiation of ART in persons with Chronic Infection without Prior ART Exposure, page 12
  - Threshold of HIV VL lowered to < 200 cp/ml in a possible exception to immediate start of ART
- Initial Combination Regimen for ART-naïve Adults, page 13
  - Deletion of the specification that 3TC/DTG may be used in the context of PrEP only if there is no documented resistance in genotypic test
- Primary HIV Infection, page 15
  - Specify that the treatment should be a 3DR and that a 2DR is not recommended
- Switch Strategies for Virologically Suppressed Persons, page 16
  - New paragraph on injectable CAB/RPV
  - Delete paragraph about dual therapy supported only by small trials
- Virological Failure, page 17
  - Add lenacapavir to the therapeutic spectrum
  - Goal of new regimen to reach within 6 months and sooner if possible
- Treatment of Pregnant Women Living with HIV or Women Considering Pregnancy, page 18
  - Change phrasing about breastfeeding which is now not recommended
  - ABC moved out from recommended regimens to alternative regimens
  - Deletion of the foot notes rising concerns about DTG and TAF during pregnancy
- ART in TB/HIV Co-infection, page 20
  - Add TAF in antiretroviral regimens in TB/HIV co-infection
- PEP, page 22
  - Lighten recommendation of PEP in case of receptive oral sex with ejaculation and not on PrEP or low PrEP adherence
- PrEP, page 23
  - Need of a fourth generation HIV test before starting PrEP
  - Recommendation of vaccination for all persons under PrEP
  - Suggestions to propose doxycycline on a case by case basis
  - New paragraph on the different drugs available for PrEP
  - Precision about population with the highest risk of adverse renal outcomes under PrEP
  - New paragraph on PrEP to PEP transition with specification of what is defined as low adherence

## DDI section

- The section on long-acting cabotegravir and rilpivirine has been expanded to indicate factors that can potentially impact the drug release from the depot and factors that can increase the risk of virologic failure. The section includes also dosing recommendations in case of missed injections, page 26
- The capsid inhibitor lenacapavir administered subcutaneously every 6 months in combination with other antiretrovirals has been added to all DDI tables
- A novel table has been added for DDI between antiretrovirals and anti-infective drugs for opportunistic infections and sexually transmitted infections, page 35
- All DDI tables have been updated to include changes implemented in the HIV drug interaction website (University of Liverpool) in the past year
- A novel resource has been added for drug classes to deprescribe in older person with HIV in presence of certain conditions, page 60

## Co-morbidity section

- A new section on the use of Patient Reported Outcome Measures has been added, page 115
- A new section on alcohol use has been added, page 63
- Updated guidance on the management of cognitive and central nervous system symptoms in persons with HIV
- Updated guidance to the travel section
- Updated guidance on management of sexual and reproductive health
- Updated guidance on management of type 2 diabetes mellitus
- Updates to cancer screening including anal cancer are included
- Updates on deprescribing in persons with HIV are included
- Updated guidance on managing chronic lung disease

## Viral Hepatitis Co-infections section

- Screening for complications
  - HCC screening recommendations have been updated with special regard to validation of PAGE-B-score in persons with HIV.
  - For Hepatitis B vaccination the use of the more immunogenic vaccination Heplisav B should be considered where available with the aim to potentially reach better responses.
- Treatment and Monitoring of Persons with HBV/HIV Co-infection
  - Caution is warranted when switching from a TDF/TAF-based regimen to drugs with a lower genetic barrier, e.g. FTC or 3TC, and persons with HIV with isolated Anti-HBc concerning viral breakthrough or relapse of HBV. Transaminases and HBV-DNA should be checked regularly
- Management of Recently Acquired HCV Infection
  - The algorithm for the management of acute HCV-infection has been removed as current guidelines recommend immediate treatment of all persons with HIV with recently acquired HCV.

## Opportunistic Infections and COVID-19 section

- A section on clinical features and treatment of Mpox has been added, page 152
- COVID-19 section has been extensively modified according to the updated evidences from literature, page 151
- TMP-SMX has been moved from “alternative” to additional “preferred” treatment in toxoplasmic encephalitis. In addition, considerations on diagnostic value of toxoplasma PCR in CSF and corticosteroids use in the context of large lesions with mass effect have been added
- WHO-recommended single-dose liposomal amphotericin B+fluconazole regimen has been added as additional “preferred” regimen in resource limited settings for the treatment of cryptococcal meningitis. In addition, recommendations on primary prophylaxis have been reformulated
- Liposomal amphotericin B+mittefosine has been added as alternative regimen for the treatment of visceral leishmaniasis
- Recommendations on the ART initiation in the context of TB and cryptococcal meningitis have been reformulated, page 134
- Hyperlinks to the table describing drug-drug interactions between selected anti-infective agents and ART have been added
- A comment on desensitization in the context of non-severe TMP-SMX allergy has been added
- Minor stylistic changes and rephrasing were made throughout the text

## Paediatric HIV Treatment section

- Updated table 1 “Preferred and Alternative First Line Options in Children and Adolescents” to include the most recent treatment options for children
- Removed table 2: Antiretroviral Formulations Useful for Paediatric and Adolescent Dosing and Administration due to redundancy
- Added section on “General principles of postnatal prophylaxis and infant feeding”, page 157
- Minor edits in the other sections

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Imprint

Publisher  
Panel Chairs

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Graphic Design

Layout

Version, Date

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Jürgen Rockstroh and Juan Ambrosioni  
Notice Kommunikation & Design, Zurich  
SoPink, Brussels  
12.0, October 2023  
EACS, 2023